UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: Pharmaceutical Industry Average Wholesale Price Litigation	MDL No. 1456
This Document Relates to:	Civil Action No. 01-12257-PBS
U.S. ex rel. West v, Ortho-McNeil Pharmaceutical, Inc. et al., No. 03-8239 (N.D. Ill.)	Hon. Patti B. Saris

SECOND AMENDED COMPLAINT

Plaintiff-Relator, Edward West, by and through his attorneys SimmonsCooper LLC, Korein Tillery and Robin Potter & Associates, P.C., on behalf of the United States, of the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Massachusetts, the State of Nevada, the State of Tennessee, the State of Texas, the State of Virginia, and the District of Columbia (collectively "the States"), for his Second Amended Complaint against defendants Ortho-McNeil Pharmaceutical, Inc. and Johnson & Johnson, pursuant to this Court's Order dated February 19, 2008, alleges based upon his personal knowledge, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendants Ortho-McNeil Pharmaceutical, Inc.("Ortho-McNeil") and its parent corporation, Johnson & Johnson, and/or their agents,

employees and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 *et seq.*, as amended ("the FCA" or "the Act").

2. From at least 1997, Ortho-McNeil has illegally promoted two of its prescription medications, Levaquin and Ultram, through the use of false and fraudulent statements and conduct. Using a combination of illegal cash incentives and kickbacks, as well as misrepresentations about the efficacy of these drugs, Ortho-McNeil has improperly induced a large number of physicians across the country to prescribe these medications for patients who are insured by state and/or federal health programs including Medicare and Medicaid.

3. Ortho-McNeil has offered illegal remuneration and kickbacks to medical providers in various forms, including but not limited to: (1) "grants" to hospitals to keep Levaquin on hospital formularies in place of less expensive antibiotics, (2) payments to high-prescribing physicians for "research" studies that provide impose minimal obligations on the physician and provide no research of value to Ortho-McNeil, (3) valuable gifts including web site design and maintenance, and (4) improper gratuities including "speaking" fees, "research" grants, trips, dinners and golf outings. In addition, Ortho-McNeil employees have illegally promoted Levaquin and Ultram by making exaggerated and misleading claims about the efficacy of the drugs for therapeutic purposes not approved by the FDA. Ortho-McNeil's marketing efforts with Levaquin have been particularly effective, and Levaquin's annual sales revenues exceed $1 billion.

4. This success, however, is in part the result of marketing and promotional activities that are prohibited by federal laws. These laws are intended to ensure that physicians prescribe medications based upon informed, impartial medical judgment -judgment on which Medicare, Medicaid and various other federal health insurance programs rely in reimbursing for

prescription drugs. Ortho-McNeil is circumventing these laws by giving kickbacks, disguised as legitimate payments, to providers in order to influence their prescribing practices. Through these and other unlawful practices described below, Ortho-McNeil has defrauded Medicare, Medicaid and other federal health care programs across the country of the informed, impartial judgment of medical professionals. As a result, Ortho-McNeil has caused these programs to pay false or fraudulent claims for reimbursement of prescriptions that would not have been paid but for Ortho-McNeil's illegal business practices.

5. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive, and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization, Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Governments behalf.

6. The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

7. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the Complaint be filed under seal for a minimum of 60 days

(without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

8. As set forth below, defendants' actions alleged in this Complaint also constitute violations of the California False Claims Act, Cal. Govt. Code § 12650 et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.0001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 et seq.

9. Based on these provisions, qui tam plaintiff and relator Edward West seeks through this action to recover damages and civil penalties arising from Ortho-McNeil's making or causing to be made false or fraudulent records, statements and/or claims in connection with its kickback-driven sales of Levaquin and Ultram. Although Ortho-McNeil did not directly submit reimbursement claims for prescriptions to federal health insurance programs, it knew that its illegal marketing practices would cause the submission of thousands of claims that were not eligible for program reimbursement.

II. PARTIES

10. Edward West, a resident of Chicago and a former sales representative for Ortho-McNeil, is the Plaintiff/relator in this action (hereafter "Plaintiff" or "relator").

11. Defendant Ortho-McNeil, headquartered in Raritan, New Jersey is a wholly-owned subsidiary of Johnson & Johnson. Ortho-McNeil was formed in 1993 by the merger of Ortho Pharmaceutical Corporation and McNeil Pharmaceutical Corporation. Defendant Johnson & Johnson, headquartered in Brunswick, New Jersey, has 200 operating companies in 54 countries around the world. Johnson & Johnson products include a variety of health care products and services. Ortho-McNeil employs about 3500 persons while Johnson & Johnson employs more than 108,000 persons worldwide.

III. JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

13. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, or transact or have transacted business in the Northern District of Illinois

14. Venue is proper in the Northern District of Illinois pursuant to 31 U.S.C. §3732(a) because the defendants can be found in and transact or have transacted business in this district. At all times relevant to this Complaint, defendants regularly conducted substantial business within this district, maintained employees and offices in this district, and made significant sales within this district. In addition, statutory violations, as alleged herein, occurred in this district.

IV. BACKGROUND

15. Ultram (tramadol) is an analgesic that was approved in 1994 for moderate to moderately severe pain. While Ultram is not a narcotic, patients who have used Ultram may suffer from withdrawal symptoms, including anxiety, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, sweating, piloerection and rarely hallucinations.

16. Levaquin (levofloxacin) is an antibiotic in the fluoroquinolone class. In December 1996, the FDA cleared Levaquin for the treatment of adults with community-acquired pneumonia, acute maxillary sinusitis or acute bacterial exacerbation of chronic bronchitis. Since then, Levaquin has also been approved for the treatment of skin infections, upper respiratory tract infections, and urinary tract infections. By 2002, Levaquin was the 63rd best selling drug in the country with annual sales topping $1 billion.

17. Levaquin is administered in through intravenous injection or in tablet form.

18. Fluoroquinolones are relatively expensive antibiotics. In 2001, Cipro the largest selling fluoroquinolone has an average wholesale price ("AWP") of $65.41 for a seven day course of treatment with tablets, while Levaquin's AWP for a 7day course of treatment was $62.13.

19. In late 1999, Bristol-Myers Squibb obtained FDA approval of a new fluoroquinolone, Tequin. Tequin, like Levaquin, was available in both injectable and tablet format, and was less expensive than Levaquin.

20. In the late 1990's, Ortho-McNeil had aggressively marketed Levaquin with considerable success. However, Tequin's lower price required that these marketing efforts become even more aggressive. As alleged below, to gain and maintain an edge in the lucrative

fluoroquinolone market, Ortho-McNeil resorted to marketing strategies prohibited by federal law, including kickback schemes and misleading promotion.

21. Ortho-McNeil maintains a nationwide marketing and sales force. The sales force is overseen through regions, each of which is organized into sales districts. Each sales district is directed by a District Manager who typically will manage 10 to 11 local sales representatives (who often work in two person teams) in that territory. Each region is headed by a Regional Business Director. There are typically 33 to 39 districts in a region. Sales representatives receive incentive-based compensation that includes an annual salary, plus a bonus. The bonus is determined by the sales representative's performance in the relevant market, including satisfying or surpassing sales targets. Accordingly, the more Levaquin and Ultram sold by providers for whom an Ortho-McNeil sales representative is responsible, the higher the sales representative's compensation will be.

V. APPLICABLE LAW

A. Prescription Drug Reimbursement Under Medicare, Medicaid and Other Federal Health Care Programs

22. Medicare provides for payment of certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease. While Medicare, with certain very limited exceptions, does not reimburse for self-administered medications, Medicare Part B, does reimburse for drugs that cannot be self-administered and that are reasonable and necessary for the diagnosis or treatment of illness. Thus, when Levaquin is administered (other than on an inpatient basis) in its injectable formulation, it is reimbursed by Medicare. Reimbursement claims for Levaquin are filed under code J1956. While each Medicare carrier sets its own reimbursement amount, the reimbursement for a 250mg dose of Levaquin IV was

approximately $19.00. Since Levaquin IV is typically administered in 500mg doses, the Medicare reimbursement would be approximately $38 per treatment.

23. Medicaid is a public assistance program providing for payment of medical expenses for the poor and disabled. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States. Medicaid reimburses both for drugs administered by providers and self-administered prescription drugs.

24. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. §§1396 et seq.

25. Federal reimbursement for prescription drugs under the Medicaid program is available for "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. §/396r-8(k)(3).

26. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/ TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

27. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of personnel

Management, provides health insurance for federal employees, retirees, and survivors. Coverage of prescriptions under these programs is similar to coverage under the Medicaid program.

28. Various statutory pricing formulas determine the payment for prescription drugs under government health care programs. In each instance, the pricing formula depends upon the integrity of price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The major programs include the following:

1. Medicaid Program And The Medicaid Rebate Obligation.

29. Medicaid is a public assistance program providing payment of medical expenses for low-income and needy persons. It covers approximately 44 million individuals, including children, the aged, blind, and/or disabled, and people who are eligible to receive federally assisted income maintenance payments. Funding for Medicaid is shared between the federal and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other health care program in the United States.

30. In order to curb mounting Medicaid drug expenditures, Congress created the Medicaid drug rebate program under the Omnibus Budget Reconciliation Act in 1990. The intent of the drug rebate program was to ensure that Medicaid have access to the same discounts and price concessions that are obtained by prescription drug manufacturers' most favored commercial customers.

31. In order to receive Medicaid reimbursement for outpatient prescription drugs, Ortho-McNeil and other manufacturers are required to enter into a Medicaid Rebate Agreement with the United States Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HFCA"), which administers the Medicaid program on behalf of the states. Social Security Act

§1927(a)(1), 42 U.S.C. §1396r-8(a)(1). The rebate amount is based upon the difference between the "Average Manufacturer Price" and the "Best Price" for each "covered outpatient drug," multiplied by the total number of units of each drug paid for by the states during the quarterly rebate period. See 42 U.S.C. §1396r-8(c)(1)(A).

32. The Average Manufacturer Price ("AMP") is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade; after deducting customary prompt payment discounts." 42 U.S.C. §1396r-8(k)(1). The Best Price is "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States." 42 U.S.C. §1396r-8(c)(1)(C)(i.). The Best Price includes all discounts, rebates, or other price concession. 42 U.S.C. §1396r-8(c)(1)(C)(ii). Payments made to providers to keep drugs on formulary should, for example, be included in the Best Price calculation. The minimum rebate amount is 15.1 percent of the Average Manufacturer Price. 42 U.S.C. §1396r-8(c)(1)(B)(i.).

33. Manufacturers are required to report their Average Manufacturer Price and Best Price for each covered drug to CMS within 30 days of each quarterly rebate period. 42 U.S.C. §1396r-8(b)(3)(A)(i.).

34. The rebate payment is the last step in the Medicaid reimbursement process. That process typically works in the following manner. Beneficiaries submit prescriptions to their pharmacy. The pharmacy submits a claim for reimbursement to the state Medicaid program. The claim indicates the manufacturer of the drug and the dosage dispensed. The state Medicaid office reimburses the pharmacist using payment levels established by CMS.

35. Data accumulated by state Medicaid offices is submitted quarterly to each participating manufacturer holding a rebate agreement with Medicaid. The quarterly data provided by state Medicaid offices to the manufacturer include the total number of dosage units of each of the manufacturer's drugs that has been dispensed to Medicaid beneficiaries in that state during the quarter. This information is used to calculate the rebate (using the formula described above), which the manufacturer is required to the state.

36. When the Medicaid usage of a drug is extremely high, as is the case with drugs like Levaquin, the manufacturer's Medicaid rebate liability is typically millions of dollars. In these circumstances, Ortho-McNeil had a financial incentive to distort and manipulate sales and price data submitted to the government in order to conceal and avoid the full extent of its Medicaid rebate obligation.

2. Programs Administered By The Department of Veterans Affairs

37. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

38. The Veterans Health Care Act of 1992 ("VHCA") established the "federal ceiling price" ("FCP"), limiting the price manufacturers can charge for drugs purchased by the VA, the Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard (referred to as the "Big Four" agencies). 38 U.S.C. §8126. Under this statute, manufacturers must enter into a "pharmaceutical pricing agreement" with the VA (executed by the VA on behalf of the Big Four), pursuant to which the manufacturer agrees that the prices charged to the Big Four for the manufacturer's covered outpatient drugs will not exceed a

maximum price of 24 percent below the non-federal average manufacturer's price ("non-FAMP"), minus any discounts, rebates or similar reductions. See 38 U.S.C. §8126(a)(2). This maximum price, is the "federal ceiling price" and is the highest price that can be charged to the Big Four agencies for covered drugs.

39. As with the pricing benchmarks discussed above, the manufacturer's non-FAMP is a self-reported price and depends on the integrity of the manufacturers' data collection and reporting. The non-FAMP is calculated using the weighted average price paid by non-federal wholesalers over the previous 12 months. A manufacturer that does not report the full extent of discounts and rebates given to its wholesale customers inflates the FCP calculation which, in turn, increases the prices paid by the Big Four agencies for the manufacturer's drugs.

40. The VHCA also requires manufacturers of brand name drugs to make all of their covered pharmaceutical products available on the Federal Supply Schedule ("FSS"), a listing of goods available for sale mainly to federal government agencies. 38 U.S.C. §8126(a)(1). All federal agencies (and a few other entities) may purchase pharmaceuticals from the FSS. The VA's National Acquisition Center is the sole negotiator for the government in establishing the prices for the approximately 25,000 drugs listed on the FSS. By regulation, drug prices on the FSS must be equal to or better than the best price charged to the manufacturer's most favored non-federal customers.

41. The FCP and FSS prices are not necessarily the same. However, if the FSS price is higher than the FCP, the Big Four agencies are not required to pay more than the FCP.

3. Department of Defense Programs

42. The Department of Defense ("DOD") provides prescription drug coverage to approximately eight Million active duty personnel, retirees; and their families through three

points of service: military treatment facility outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program. As described above, DOD is covered by the federal ceiling price established by the VHCA.

43. Although some pharmaceutical purchases are made through the FSS, DOD also negotiates independent contracts for the majority of its purchases. The pharmaceutical division of the Defense Supply Center in Philadelphia is the single entity that negotiates DOD's distribution and pricing agreements with over 200 drug manufacturers. The starting point for the negotiations is the FCP, i.e., the 24 percent discount off the manufacturer's average non-federal price, as required by the VHCA.

4. Public Health Service Entities

44. Drug prices to entities funded by the Public Health Service (including, for example, public housing health centers, disproportionate share hospitals, black lung clinics, urban Indian organizations, AIDS clinics, and AIDS drug purchasing assistance programs) are set according to a statutory formula equal to the "Average Manufacturer Price" for the drug less the amount of the Medicaid rebate. Public Health Service Act §340B(a)(1), 42 U.S.C. §256b(a)(1). Under this formula, manufacturers who conceal and avoid paying the full amount of their Medicaid rebate obligation also cause the price for that drug to Public Health Service entities to be inflated.

B. False, Fraudulent And Misleading Price And Sales Data Are A Major Source Of Fraud And Abuse In Government Health Care Programs

45. Concern about fraud and abuse in federal health care programs prompted the Inspector General of the Department of Health and Human Services in May 2003 to issue a special "Guidance" for pharmaceutical manufacturers, entitled, "OIG Compliance Program Guidance For Pharmaceutical Manufacturers." 68 Fed. Reg. 23731 (May 5, 2003). The Guidance

identifies a number of practices that violate the False Claims Act and other federal fraud and abuse statutes and regulations. See id. at 23733.

46. The Guidance states that one of the "areas of significant concern" to the government enforcement community is the "integrity of data used by state and federal governments to establish payment amounts" for covered drugs under Medicaid, Medicare, and other government health care programs. Id. The Guidance explains:

> Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturers product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Id.
> The Guidance further provides:
>
> [M]anufacturers' reported prices should accurately take into account price reductions, rebates, up-front payments . . . or other price concessions or similar benefits offered to some or all purchasers.
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> Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks . . . .manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs.
>
> In sum. pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes. (Emphasis added.)

Id. at 23733-34.

C. The Anti-Kickback Statute

47. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically inappropriate, unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

48. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

49. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a7a(a)(7).

50. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices

that violate the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the suspect practices cited by the Inspector General were drug companies' payment of "research grants" to substantial prescribers of its medications; payments to physicians for "studies" of the company's products when the studies were "of questionable scientific value and require little or no actual scientific pursuit"; and payments to physicians who had offered no particular services of benefit to the drug company but who had generated in the past, or had the potential to generate in the future, a large volume of business for the drug company. Id.

51. The Inspector General's May 2003 Guidance identified in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" infecting federal health care programs. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). The 2003 Guidance cautions manufacturers against engaging in the following suspect practices including:

1. Improper Consulting and Advisory Payments: These are payments made pursuant to less than bona fide consulting or advisory arrangements, such as payments to physicians for simply attending meetings or conferences in a passive capacity, or for services connected with a manufacturer's marketing activities.

2. Improper Business Courtesies and Other Gratuities: These are gifts such as merchandise of more than trivial value, entertainment, recreation, travel, meals, and other gratuities furnished in association with information or marketing presentations.

3. Improper Educational and Research Funding: This refers to funding for research or education that is initiated or influenced by the manufacturers' sales or marketing departments. Id. at 23731-39.

52. This OIG Guidance also makes it clear that while the Anti-Kickback law does not prohibit discounts, the OIG expects that the seller make it clear to its customers that the customer may have reporting requirements with respect to the discount.

53. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

54. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, hospitals, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

55. Any party convicted under the Anti-Kickback statute must be excluded (i.e., not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

56. The enactment of these various provisions and amendments demonstrates Congress's commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from the public fisc for the resulting claims.

D. FDA Prohibition on Misleading Promotion of Pharmaceuticals

57. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

58. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which must also be reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d).

59. The FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. See 21 U.S.C. §§ 331, 352, 355(d). This regulatory scheme protects patients and consumers by ensuring that drug companies do not make claims as to the safety or efficacy of an approved drug unless the claim is proven through scientific evidence to the satisfaction of the FDA.

60. The FDA also specifically regulates prescription drug advertising. Under the Food and Drug laws, a manufacturer illegally "misbrands" a drug if it advertises the drug in a manner inconsistent with the product's approved labeling. See 21 U.S.C. §§ 352; 21 C.F.R. § 201.128. Under this statutory authority, the FDA requires prescription drug advertisements to be accurate, balanced, and nonmisleading in their claims of safety and efficacy. This is accomplished through a comprehensive surveillance, enforcement, and education program overseen by the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC").

61. FDA interprets the term "advertisement" broadly, to include not only written information promoting the product, but also oral statements made by manufacturers' sales and marketing agents. See "[FDA] Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,075-76 (1997); 21 C.F.R. §201.128. On a number of occasions, DDMAC has prohibited manufacturers from making unsubstantiated efficacy claims similar to those made by Ortho-McNeil's sales representatives, described in paragraphs 90 and 101 below.

VI. ORTHO-McNEIL'S UNLAWFUL MARKETING STRATEGY

A. Ortho-McNeil Utilizes a Wide Array of Kickbacks and Unlawful Remuneration to Medical Providers to Increase Sales

62. Beginning in 1997 when the FDA first approved Levaquin, Ortho-McNeil embarked on an aggressive strategy of paying kickbacks and unlawful remuneration to physicians and other medical providers to capture a share of the fluoroquinolone market then dominated by Cipro, produced by Bayer Pharmaceutical. The results of Ortho-McNeil's illegal marketing campaign have been extraordinarily successful. By 2002, 61% of hospital patients

with pneumonia were treated with Levaquin. And by late 2001, Levaquin held approximately a 40% share of the fluoroquinolone market generally.

63. Levaquin's marketing strategy, described below, however, violates the federal Anti-Kickback statute. Furthermore, because its kickback-induced prescriptions are not entitled to reimbursement from Medicaid and other federal health care, programs, such claims for reimbursement also violate the False Claims Act. In addition, this marketing strategy led Ortho-McNeil to improperly report its prices to Medicaid and other federal health programs. As a result of Ortho-McNeil's conduct, many millions of dollars in reimbursement payments have been collected from the United States in violation of the law.

64. To carry out its unlawful marketing strategy, Ortho-McNeil created an array of monetary incentives and kickbacks to influence the prescribing practices of medical providers. These unlawful inducements and kickbacks include, but are not limited to, the following:

1. Payments to Hospitals to Keep Levaquin on Formulary

65. In 1999, with the introduction of Tequin, which was less expensive than Levaquin, hospitals began considering whether to substitute Tequin for Levaquin on their formulary. Because the price paid by a hospital for a drug decreases as the hospital's market share of drug increases, hospitals could maximize their savings by stocking only Tequin instead of Levaquin.

66. Ortho-McNeil understood that if they tried to compete with Tequin by lowering the price of Levaquin at hospitals, Ortho-McNeil would be forced to lower the reimbursement level for Levaquin for government programs since most government reimbursement for drugs takes into account the lowest price at which the drug is offered. To avoid lowering the cost of Levaquin to hospital formularies, Ortho-McNeil began offering monetary inducements to

persuade hospitals not to switch from Levaquin to Tequin. While some of these payments may have been labeled as "educational grants" they had one, and only one purpose — to indirectly lower the cost of Levaquin to the hospital, and thereby induce the hospital to continue to purchase Levaquin.

67. In the spring of 2000, the pharmacist at Holy Cross Hospital in Chicago told Ortho-McNeil representatives, including relator West, that Holy Cross was going to switch from Levaquin to Tequin because Tequin was less expensive. In the summer of 2000, relator was directed by his district manager to participate in offering a $25,000 payment to Holy Cross Hospital. Relator was told by his district manager that this $25,000 would come from $5,000 payments from five separate Ortho-McNeil employees. Relator understood that these $5,000 payments would then somehow be reimbursed to the employees through their expense account. The other Ortho-McNeil employees who were to participate in the Holy Cross payment were relator's district manager, the regional manager, relator's sales team partner, and the strategic account manager who had responsibility for Holy Cross.

68. When relator questioned this instruction, he was told that a similar payment had been made to keep Levaquin on formulary at Rush-Presbyterian - St. Luke's Hospital in Chicago, and that the regional manager had received approval from Ortho-McNeil's home office to make the payment. Relator understood from this that such payments were part of an overall marketing plan to deal with the Tequin competition.

69. Relator refused to participate in the payment to Holy Cross and his employment with Ortho-McNeil was terminated.

2. Price discount to hospitals to restrict hospital formularies

70. Levaquin's price to hospitals and other institutional providers was set by negotiation between Ortho-McNeil and the provider. While the most important factor in setting price was the market share that Levaquin carried at the particular institution, Ortho-McNeil sales representatives also made price concessions in instances where the provider would agree not to continue to carry competing drugs on their formularies.

71. For example, in March 2000, Ortho-McNeil sale representative Cheryl Janicek agreed to lower the price of Levaquin to Holy Cross Hospital on the condition that the hospital "no longer stock Cipro for MD's requesting the drug." Cipro, however, is approved for treatment of illnesses and conditions for which Levaquin has not received FDA approval including, for example, anthrax, prostatitis, and febrile neutropenia. By linking a price discount to removing Cipro from the hospital's formulary, Ortho-McNeil compromised patient care.

3. Rebates to increase the Medicare profit spread for hospitals

72. Levaquin's price to hospitals and other institutional providers varied according to what part of the provider's relevant drug market share was filled by Levaquin. For example, in March 2000, the highest price a hospital would pay for a 500 mg IV of Levaquin was $32. The lowest price a hospital would pay was $19. The initial price was set according to a hospital's market share as of the previous quarter. Once the price was set, the drug was supplied to the hospital by a wholesaler at the contract price. As a result, all invoices for Levaquin would come from the wholesaler to the hospital, and all payments for Levaquin would be made by the hospital to the wholesaler.

73. The contract between Ortho-McNeil and hospitals provided that the hospital would also receive a rebate directly from Ortho-McNeil when the hospital's Levaquin use over

the year moved the hospital into a higher discount bracket. This discount would be calculated retroactively so that the hospital would receive the benefit of its lower price for all Levaquin – both IV and tablets – that it had purchased over the course of the year.

74. Although the invoices for the Levaquin that the hospital purchased at the contract price came from the wholesaler, the rebate checks to the hospital were cut directly by Ortho-McNeil, and were presented personally to the hospital by Ortho-McNeil sales representatives. These checks typically ran into the tens of thousands of dollars.

75. Ortho-McNeil sales representatives were instructed to tell the hospital employees to whom they delivered the rebate checks that since the checks came directly from Ortho-McNeil, there would not be an accounting record available from the wholesaler that tracked the price, and that the hospital therefore could easily hide the fact that it received a rebate from Medicare and Medicaid. Relator believes that the intent of this instruction was to induce the hospitals to purchase Levaquin by offering hospitals an opportunity to take a hidden profit on Levaquin.

76. From 1997 to 2000, the Average Wholesale Price for 500 mg of Levaquin IV was $39.60.[1] Ortho-McNeil employed a multi-tiered rebate system, whereby purchasers (such as hospitals) would pay the highest rate for 500 mg of Levaquin IV, which was $32, throughout the year. During the final quarter of the year, if the purchaser's market share reached a certain level, Ortho-McNeil would retroactively apply a discount to the price for the entire year and give the purchaser a cash rebate for the difference. This multi-tiered rebate system was comprised of eight levels of pricing ($32, $31, $29, $27, $25, $23, $21 and $19), with lower prices being given to purchases with larger market share. Based on the published AWP of $39.60, the "spread" between what the purchasers paid for the 500mg of Levaquin IV and the AWP exceeded 30% for

[1] This information was obtained from the 1997-2004 *Redbook*, published by Thompson Healthcare.

all purchasers who paid from $29 to $19. In fact, this "spread" was 36.6% for purchasers paying $29 per dose for 500mg Levaquin IV and increased to 108% if the purchaser received the highest discounted rate of $19 per dose.

77. For example, when taking into account the rebates, discounts, and other incentive payments, Holy Cross Hospital in Chicago was in the $21 pricing tier. In other words, in 1999 Holy Cross Hospital paid $21 per 500mg Levaquin IV dose, which represents a spread based on the fraudulent 1999 AWP of $39.60 of 88.6%.

78. Relator also alleges on information and belief Ortho-McNeil did not accurately and fully report the lower prices resulting from Ortho-McNeil's hospital rebate program as required by the Medicaid and other government funded programs.

4. Dividing Single Use Premix to increase profit

79. The hospitals in Mr. West's territory purchased Levaquin in both tablet and injectable formulations.

80. Most of these injectable formulations were sold as "Levaquin Injection Premix in Flexible Containers." Each of these flexible containers supplied "a single-use, premixed solution . . ." and contained "a dilute solution with the equivalent of 250 mg or 500 mg of levofloxacin."

81. As the FDA approved label makes clear, these premix formulations are supplied for a single use. To that end, the label instructs **"Since the PREMIX flexible containers are for single-use only, any unused portion should be discarded."** (Emphasis in original).

82. The typical dosage of Levaquin for respiratory illnesses is 500 mg, while the typical dosage for urinary tract infections is 250 mg.

83. The Medicare J-Code reimbursement (used for Part B reimbursement) for injected Levaquin is approximately $19 for a 250 mg dose. Ortho-McNeil apparently never sought, nor

received, a J-Code reimbursement for the more frequently prescribed 500 mg premix dose. As a result, all Part B claims for Levaquin were submitted under 250 mg dosage J-Code.

84. Until at least mid-2000, Ortho-McNeil priced the 250 mg premix at $16, an amount slightly below its Medicare Part B J-Code reimbursement. This price was not subject to a volume discount. In contrast, price for the 500 mg premix varied from $19 to $32 depending on the volume purchased by the hospital.

85. Ortho-McNeil sales representatives were instructed to explain to hospitals that because of the pricing disparity between the 250 mg bags and the 500 mg bags, the hospitals could reduce their costs if they purchased the 500 mg pre-mix, and then divided the pre-mix into two 250 mg doses as needed. Dividing the 500 mg bags into two doses violated the FDA single-use packaging limitation, and endangered the patient who received the second-use of the single use package.

86. In addition, when a 500 mg bag was sold as essentially two 250 mg doses, it meant that the actual price of the 250 mg dose went from $16 "list price" to as little as $9.50. The Medicare Part B reimbursement for that same 250 mg dose remained, however, at approximately $19.00.

87. Dividing the 500 mg pre-mix bags violated the FDA single use labeling restriction, endangering patient care, while allowing Ortho-McNeil to secretly "discount" its 250 mg doses below its established Medicare and Medicaid pricing.

5. Kickbacks Under the Guise of Speaker Fees and "Research Grants" that Impose Minimal Obligations on the Recipient

88. Ortho-McNeil also provides illegal payments to physicians who prescribe large amounts of Levaquin and Ultram. It also makes such payments to pharmacists and Phamr.D.'s on hospital staffs who influence the prescribing practices of physicians. These payments, which are

provided ostensibly for "research studies" and "speaking fees" are substantially in excess of the value of any services provided. Indeed, the primary purpose of such agreements is to secure Levaquin's position as a priority drug with these valuable prescribers.

89. For example, in 1998, Ortho-McNeil recruited several dozen urologists to join a Levaquin "Speaker Bureau." These urologists were paid hundreds of dollars per presentation to speak about Levaquin over a lunch or dinner to fellow doctors. Ortho-McNeil provided these speakers with Levaquin data and slides with which to make their presentations. Dr. Robert E. Hirschtick, Assistant Professor at Northwestern University Medical School was one of the highest paid Levaquin speakers in the Chicago area. Ortho-McNeil representative tracked the prescribing practices of these speakers so that the speakers would understand that their continued service as paid speakers was dependent on their own prescribing practices.

90. To promote Ultram, Ortho-McNeil recruited doctors and Pharm. D's to conduct lunch time audio seminars for hospital based pharmacists, doctors, and nurses to discuss Ultram. These lunch time speakers who were paid thousands of dollars had positions of substantial influence over prescribing practices in very substantial institutions. These Ultram speakers included for example, Robert L. Barkin, MBA, Pharm.D., FAC, Associate Professor of Anesthesiology, Family Medicine, Pharmacology, Faculty Orthopedic Surgery, Psychiatry at Rush Medical College in Chicago; Warren Katz, M.G., Chief of Rheumatology, Clinical Professor of Medicine, University of Pennsylvania in Philadelphia, and Gary Ruoff, M.D., Medical Director of Clinical Research, Westside Family Medical Center, Kalamazoo, Michigan.

91. Ortho-McNeil also made sizeable payments to physicians and pharmacists to serve as "consultants." Consultants were paid to conduct "research studies." While the research studies had impressive names, in reality the studies involved such "research" as giving the

consultant doctors free samples of Levaquin to provide their patients, and then asking doctors to fill in a form for each patient who received the free sample.

92. Plaintiff is informed and believes that Ortho-McNeil has similar agreements with other pharmacists, Pharm. D and high-prescribing physicians across the country to whom Ortho-McNeil makes payments in order to influence their prescribing practices with respect to Levaquin and Ultram. The identity of other recipients is contained in records within the possession of Ortho-McNeil to which Plaintiff does not have access.

6. Improper Gifts To Physicians.

93. In August of 1999, Ortho-McNeil launched a new inducement program targeted at urology practice groups who had a "high volume urology practice —preferably high Cipro and low Levaquin." These urology practices were to be offered, free of charge, a website that would be part of urologychannel.com. According to the Urologychannel's materials, the initial value of the website was between $6,000 and $10,000. In addition there was a monthly maintenance fee of $150. Ortho-McNeil sales representatives were directed to offer both the website and maintenance for a year to doctors without any charge. According to Ortho-McNeil materials the sales representatives were to "Leverage this program to build relationship and increase Levaquin business."

94. Once a doctor had signed up for the websites, sale representatives were to track the doctor's pattern of prescribing Levaquin; and then follow up with the doctor to make certain that the doctor understood that Ortho-McNeil was keeping track of the ordering practices of those doctors for whom it was providing web support. Sales representatives were later instructed that they could offer doctors a second year of free web site maintenance.

95. Each sales team was encouraged to sign up three groups for the Urologychannel. The practices who accepted the website and maintenance offered by Ortho-McNeil through relator West's team were Southwest Urology Associates in Evergreen Park, Illinois, Gersack, Demarco, Hoyme & Associates in Oak Lawn, Illinois and Dr. Herme Sylora and Dr. James A. Sylora in Evergreen Park, Illinois.

96. A second program was launched in the fall of 1999 to provide web site inducements to infectious disease, pulmonary, ENT, and allergy specialists. This second program was directed at individual doctors rather than practice groups and provided personalized WebMD sites. The object of the WebMD Program according to Ortho-McNeil documents was "to further cultivate relationships to drive share against macrolides and Augmentin." Augmentin, while not a fluoroquinolone, was an antibiotic that was commonly used to treat conditions for which Levaquin was also approved.

97. Ortho-McNeil also tracked the ordering practices of doctors who received a WebMD site, and sales representatives understood that they were to use the website promotion to encourage doctors to write additional prescriptions for Levaquin.

98. Each of Ortho-McNeil's sales teams were encouraged to enroll 40 doctors in the WebMD program. The names of the doctors who have received web sites or web support paid for by Ortho-McNeil would be contained in records within the control and custody of Ortho-McNeil to which Plaintiff does not have access.

99. In addition to giving doctors website, to promote the use of Levaquin and Ultram, Ortho-McNeil often provided physicians with free trips to conferences, expensive dinners, golf outings, tickets to amusement parks and other similar gratuities.

B. Ortho-McNeil Is Also Illegally Promoting Levaquin and Ultram for Indications Where There Is No FDA Approval.

100. Ortho-McNeil's kickbacks and illegal payments described above are just one facet of its aggressive marketing. With the knowledge and consent of marketing executives at Ortho-McNeil, sales representatives have sought to market both Levaquin and Ultram for conditions for which there has been no FDA findings of safety and efficacy. The sales representatives have a significant financial incentive to promote drugs in this unrestrained manner, since their bonus is based on their sales numbers.

101. Under the Food and Drug laws, explained above, drug manufacturers are prohibited from making exaggerated and misleading claims as to the safety and efficacy of their approved drugs. Ortho-McNeil sales representatives disregard this prohibition with respect to both Levaquin and Ultram. Examples of the types of misrepresentations made to physicians by sales representatives include, but are not limited to, the following:

1. Ortho-McNeil sales representatives were instructed to instruct physicians that Levaquin should be used to treat prostatitis despite the fact that Levaquin had not been approved by the FDA for the treatment of prostatitis.

2. Ortho-McNeil sales representatives were instructed to disseminate unsolicited articles to doctors that promote the use of Ultram for conditions for which Ultram had not received FDA approval including osteoarthritis and diabetic neuropathy. In addition, sales representatives were given articles to disseminate to doctors that recommended that Ultram be given at dose levels not approved by the FDA.

COUNT I

False Claims Act 31 U.S.C. N372904(1) and (a)(2)

102. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 101 of this Complaint.

103. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

104. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

105. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to induce the Government to approve and pay such false or fraudulent claims.

106. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

107. In addition, the prices paid for Levaquin by Medicare, Medicaid and other federal programs were inflated in that they failed to account for the inducements paid by defendants to hospitals and other provider.

108. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across the United States. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

109. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continues to pay the claims that would not be paid but for Ortho-McNeil's illegal marketing practices and illegal inducements.

110. By reason of defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims, amounting to many millions of dollars, for prescriptions that were illegally induced by defendants.

COUNT II

False Claims Act 31 U.S.C. §§3729(a)(7)

111. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

112. This is a claim for penalties and treble damages under the Federal False Claims Act.

113. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

114. As a result, monies were lost to the United States through the nonpayment or non-transmittal of money or property owed to the United States by the defendants, and other costs were sustained by the United States.

115. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

116. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

COUNT III

California False Claims Act
Cal Govt. Code §12651(a)(1) and (2)

117. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

118. This is a claim for treble damages and penalties under the California False Claims Act.

119. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

120. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

121. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the California State Government.

122. As a result, California State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the California State Government by defendants.

123. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

124. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT IV

Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1) and (2)

125. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

126. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

127. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

128. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

129. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Delaware State Government.

130. As a result, Delaware State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Delaware State Government by defendants.

131. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

132. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

COUNT V

Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

133. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above, as though fully set forth herein.

134. This is a claim for treble damages and penalties under the Florida False Claims Act.

135. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

136. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

137. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Florida State Government.

138. As a result, Florida State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Florida State Government by defendants.

139. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT VI

Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

140. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

141. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

142. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

143. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

144. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Hawaii State Government.

145. As a result, Hawaii State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Hawaii State Government by defendants.

146. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

147. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT VII

Illinois Whistleblower Reward And Protection Act
740 III. Comp. Stat. §17513(a)(1). (21

148. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

149. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

150. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

151. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

152. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Illinois State Government.

153. As a result, Illinois State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Illinois State Government by defendants.

154. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

155. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT VIII

Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1). (2)

156. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

157. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

158. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

159. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

160. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Massachusetts State Government.

161. As a result, Massachusetts State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Massachusetts State Government by defendants.

162. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

163. Additionally, the Massachusetts State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT IX

Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a). (b)

164. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

165. This is a claim for treble damages and penalties under the Nevada False Claims Act.

166. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

167. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

168. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Nevada State Government.

169. As a result, Nevada State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Nevada State Government by defendant

170. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

171. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count X

Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

172. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

173. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

174. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

175. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

176. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Tennessee State Government.

177. As a result, Tennessee State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Tennessee State Government by defendant.

178. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

179. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XI

Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

180. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

181. This is a claim for treble damages and penalties under the Texas Medicaid Prevention Law.

182. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

183. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

184. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Texas State Government.

185. As a result, Texas State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Texas State Government by defendant.

186. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

187. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XII

Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1). (2)

188. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

189. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

190. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

191. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

192. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Virginia State Government.

193. As a result, Virginia State monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the Virginia State Government by defendants.

194. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

195. Additionally, the Virginia State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XIII

District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §1-1188.14(a)(1), (2)

196. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 101 above as though fully set forth herein.

197. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

198. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

199. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

200. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia Government.

201. As a result, District of Columbia monies were lost through (a) the payment of such false and fraudulent claims and (b) the non-payment or non-transmittal of money or property owed to the District of Columbia Government by defendant.

202. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

203. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

PRAYER

WHEREFORE, Relator prays for judgment against the defendants as follows:

1. that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the counterpart provisions of the state statutes set forth above;

2 that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. §68.082(2);

6. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 III. Comp. Stat. §175/3(a);

8. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

9. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1)(a), (b);

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §71-5-182(a)(1);

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a)(1), (2);

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §1-1188.14(a)(1), (2);

14. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

15. that Relator be awarded all costs of this action, including attorney's fees and expenses; and

16. that Relator recover such other relief as the Court deems just and proper.

Respectfully submitted,

SIMMONSCOOPER LLC

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of March, 2008 I electronically filed this document with the Clerk of the Court using the CM/ECF system, which will send notification to the following:

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A copy of the foregoing also has been served on March 20, 2008 on the following individuals by depositing a copy in the U.S. mail, first-class postage pre-paid:

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